Reference number
1810-A

SPECIALTY GUIDELINE MANAGEMENT

LYNPARZA (olaparib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Ovarian Cancer

a. First-Line Maintenance Treatment of *BRCA*-mutated Advanced Ovarian Cancer
Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCA*m or s*BRCA*m) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA- approved companion diagnostic test for Lynparza.

b. Maintenance Treatment of Recurrent Ovarian Cancer
Lynparza is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy.

c. Advanced *gBRCA*-mutated Ovarian Cancer After 3 or More Lines of Chemotherapy
Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (*gBRCAm*) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA- approved companion diagnostic test for Lynparza.

2. Breast Cancer
Lynparza is indicated in patients with deleterious or suspected deleterious *gBRCAm*, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA- approved companion diagnostic test for Lynparza.

3. Pancreatic Cancer
Lynparza is indicated in patients with deleterious or suspected deleterious *gBRCAm* metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA- approved companion diagnostic test for Lynparza.

B. Compendial uses

1. Breast cancer
Recurrent or metastatic HER2-negative, BRCA 1/2-germline mutated breast cancer that is hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory.

2. Ovarian Cancer

As a single-agent maintenance therapy for patients with BRCA1/2 germline or somatic mutations who are in a complete clinical remission (no definitive evidence of disease) or in a partial remission after primary treatment for stage II-IV disease

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Documentation of laboratory report confirming BRCA mutation status, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Epithelial ovarian, fallopian tube, or primary peritoneal cancer

1. Authorization of 12 months may be granted for treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer as a single agent when all of the following criteria are met:
   a. Tumor has deleterious BRCA mutation (germline, somatic, or both) as detected by an FDA-approved companion diagnostic test
   b. Member has received three or more prior chemotherapies

2. Authorization of 12 months may be granted for the maintenance treatment of recurrent disease as a single agent when all of the following criteria are met:
   a. Members is in complete or partial response to platinum based chemotherapy
   b. Member has received at least two prior platinum-containing regimens

3. Authorization of 12 months may be granted for the maintenance treatment of BRCA mutated-Stage II-IV disease as a single agent when all of the following criteria are met:
   a. Members is in complete or partial response to platinum based chemotherapy
   b. Member has a deleterious BRCA mutation (germline, somatic, or both) as detected by an FDA-approved companion diagnostic test

B. Breast Cancer

Authorization of 12 months may be granted for the treatment of human epidermal growth factor receptor 2 (HER2)-negative recurrent or metastatic breast cancer as a single agent in members with deleterious or suspected deleterious germline BRCA mutations.

C. Pancreatic Cancer

Authorization of 12 months may be granted for the maintenance treatment of deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma as a single agent, in members whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced disease progression or an unacceptable toxicity. For the first-line maintenance treatment of BRCA-mutated advanced ovarian cancer in a complete response, the maximum treatment duration is 2 years.

V. REFERENCES

1. Lynparza® Tablets [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2019.
2. The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 07, 2020.
3. The NCCN Clinical Practice Guidelines in Oncology® Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer (Version 3.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 07, 2020.
4. The NCCN Clinical Practice Guidelines in Oncology® Breast Cancer (Version 3.2019). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 07, 2020.
5. The NCCN Clinical Practice Guidelines in Oncology® Pancreatic Adenocarcinoma (Version 01.2020). © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 07, 2020.